

Credentialing and Privileging Proposed Rule from Centers for Medicare and Medicaid Services

On May 26, the Centers for Medicare and Medicaid Services (CMS) unveiled its long awaited proposed rule that would make changes in CMS's Conditions of Participation (CoPs) as they apply to the credentialing and privileging of telehealth providers.

The CMS rule makes numerous changes in the CoPs that are intended to allow a streamlined procedure for the credentialing and privileging of telehealth practitioners at the originating site (location of the patient). Most importantly, the proposed rule seeks to permit the originating site to use the credentialing and privileging decisions of the distant site (location of the practitioner) under certain circumstances.

The proposed rule is open for public comment until July 26, 2010. A copy of the proposed rule can be found at:

>>> http://www.telehealthlawcenter.org/data/2010-12647.pdf

<u>Background on Credentialing and Privileging</u> of Practitioners in Medicare Participating Hospitals

Hospitals (non Critical Assess)

The current CMS CoPs "require the government body of the hospital to make all privileging decisions based upon the recommendations of its medical staff after the medical staff has thoroughly examined and verified the credentials of practitioners applying for privileges, and also used specific criteria to determine whether an individual practitioner should be privileged at the hospital" [42 CFR §482.12 (a) (2) and §482.22 (a) (2)].

Hospitals (Critical Access)

The current CoPs pertaining to critical access hospitals (CAH) "require every CAH that is a member of a rural health network to have an agreement for review of physicians and practitioners seeking privileges at the CAH." [42 CFR 485.616 (b)].

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This agreement must be with a hospital that is a member of the network, a Medicare Quality Improvement Organization or another qualified entity indentified in the State's rural health plan. The services that all physicians provide, whether in person or remotely through telemedicine, must be evaluated by one of these three outside entities.

According to the proposed rule, "CMS regulations currently require hospitals and CAHs receiving telemedicine services to privilege each physician or practitioner providing services to its patients as if such practitioner were on-site."

Current CMS regulations allow the use of third party credentialing verification organizations to assist with the compilation and verification of the credentials of a practitioner applying for hospital privileges.

Privileging decisions at CAHs are required by either "the governing body or the person responsible for the CAH."

The Joint Commission Telemedicine Standards

Recognizing the bureaucratic and financial burden of credentialing and privileging each telemedicine practitioner at each originating hospital, in 2004, working closely with the telemedicine community, The Joint Commission (TJC/JC) implemented standards for the credentialing and privileging of telemedicine practitioners.

These telemedicine standards allowed JC-accredited hospitals to rely on the credentialing and privileging decisions of other JC-accredited facilities for telemedicine practitioners. This process was commonly referenced as "credentialing and privileging by proxy."

It is important to note that TJC telemedicine standards are voluntary. A hospital that prefers to credential and privilege each telemedicine practitioner can do so. The "proxy" process is available only for those hospitals choosing to use it for their telemedicine program.

While TJC telemedicine standards have been in effect since 2004, these standards were not recognized by CMS as having met or exceeded the Medicare CoPs. As noted in the proposed rule, "Hospitals that have used this method to privilege distant-site medical staff technically did not meet CMS requirements that applied to other hospitals even though they were TJC-accredited. When CMS learned of specific instances of such noncompliance, through on-site surveys by State Survey Agencies, the hospital was required to change its policies to become compliant."

Congress gave CMS the authority to implement a program "that allows private, national accreditation organizations to 'deem' that a Medicare participating organization is compliant with certain Medicare requirements. Six areas are "deemable": quality assurance, antidiscrimination, access to services, confidentiality and accuracy of enrollee records, information on advance directives, and provider participation rules." [The Balanced Budget Act of 1997 (BBA) and of the subsequent Balance Budget Refinement Act of 1999 (BBRA)]

To be approved for deeming authority, an accrediting organization must demonstrate that their program meets or exceeds the Medicare requirements for which they are seeking the authority to deem compliance. [Source: CMS website]

Until 2008, TJC held permanent "deeming authority" through statutory language authorized by Congress. However, the Medicare Improvements for Patients and Providers Act of 2008 [Public Law 110-275, Section 125] terminated TJC's permanent statutory deeming authority effective July 15, 2010.

In order to continue to hold CMS deeming authority, TJC was required to reapply to CMS for deeming authority and bring all JC standards into compliance with CMS guidelines and regulations. This included bringing the standards for the credentialing and privileging of telehealth providers into compliance with CMS's CoP.

Joint Commission Application for Deeming Authority Approved

On November 27, 2009, CMS published in the Federal Register its decision to approve the TJC's application for continued deeming authority for hospitals, effective July 15, 2010.

[Source: http://edocket.access.gpo.gov/2009/E9-27973.htm]

In acknowledging that TJC's telemedicine guidelines would be modified to be in compliance with CMS's CoPs, the approval notice referenced the following:

To meet the requirements at Sec. 482.12(a)(2) and Sec.482.22(c)(4), the Joint Commission revised its elements of performance (EPs) to require that all licensed independent practitioners who provide for the patient's care, treatment, and services in an accredited hospital via telemedicine are credentialed and privileged at the originating site. If the distant site is a Medicare-participating hospital, the originating site's medical staff may use a copy of the distant site's credentialing packet for privileging purposes. This packet includes all credentialing documents, a list of all privileges granted to the licensed independent practitioner by the distant site, and an attestation signed by an appropriate official of the distant-site hospital, indicating that the packet is complete, accurate, and up-to-date.

On July 15, 2010, TJC's credentialing and privileging by proxy guidelines would no longer be in effect.

Input from the Telemedicine Community

This decision to require each originating hospital to credential and privilege each telemedicine practitioner quickly became the most pressing obstacle facing the future of telemedicine. It was clear that it threatened telemedicine programs from two angles:

- First, the impact on often smaller, originating site hospitals without the financial or staffing resources to implementing full credentialing and privileging on all telemedicine practitioners. Additionally, for these smaller facilities, many felt this change would impact patient safety. Most often, an originating site hospital sought a specialist through telemedicine because they did not have that expertise on staff. Yet, in order to grant privileges in accordance with CMS's CoPs, these same hospitals would be called upon to render a professional judgment on these same telemedicine practitioners who they sought out because they didn't have that expertise on staff.
- Second, is the issue of the credentialing and privileging process on the telehealth practitioners themselves. For many telemedicine programs, credentialing and privileging at each originating site would be a significant bureaucratic and financial burden. The initial reaction to the CMS decision was the possibility of the termination of telemedicine programs because the physicians themselves did not want to undergo what they viewed as duplicative, credentialing and privileging at multiple originating sites.

Over the course of a year, there were many attempts by the telemedicine community to raise the level of visibility with CMS, Congressional representatives, and Executive Branch officials. Some of these activities included:

• Rep. Richard Boucher (D-VA), a senior member of the House Energy and Commerce Committee (one of the House Committee's with health care jurisdiction) spearheaded a letter signed by other members of the House of Representative to CMS alerting agency officials to the impact of the CMS CoPs on the delivery of telemedicine and urging the agency's reconsideration of implementing a credentialing and privileging policy that would severely impact telemedicine programs nationwide.

The Telehealth Leadership Initiative collected the signatures of over 375 individuals on a similar letter to CMS.

- Reps. Mike Thompson (D-CA), Bart Stupak (D-MI), Sam Johnson (R-TX), and Terry Lee (D-NE) introduced HR 2068, the *Medicare Telehealth Enhancement Act of 2009*. HR 2068 included a number of provisions pertaining to telehealth, including a section on the telehealth credentialing and privileging issue. Even though it wasn't included in the final health care reform bill, credentialing and privileging language was included in the final health care reform version passed by the House of Representatives.
- Senator Tom Udall (D-NM) introduced an amendment to the Senate version of health care reform that included language intended to delay the impact of the July 15th deadline and direct CMS to engage in rulemaking to provide a streamlined process for credentialing and privileging telemedicine providers.
- Lead by Dr. Karen Rheuban, President of the American Telemedicine Association and CTeL Board member, CTeL and ATA attended two high level meetings with CMS officials. These included a meeting arranged by Rep. Boucher with the top Obama Administration CMS appointee, Marilyn Tavenner. As Principal Deputy Administrator, Ms. Tavenner is the second ranking official within CMS. The Center for Telehealth and e-Health Law (CTeL) attended in a technical advisory capacity.

In addition, a meeting was held between telehealth officials and Mr. Jonathan Blum, the CMS Director for Medicare Management.

• At the direction of Administrator Tavenner and the invitation of Dr. Rheuban, Dr. Barry Straube, CMS's Chief Medical Officer and Director of the Office of Clinical Standards & Quality, and Jeannie Miller, Deputy Director, Clinical Standards Group, traveled to the University of Virginia (UVA) to hear directly from officials from a telemedicine program about the process for credentialing and privileging telehealth practitioners and the impact of the CMS decision. In attendance at this meeting were officials from the ATA, CTeL, top officials from a critical access hospital, members of the UVA telemedicine network, and other UVA officials, such as the chairman of the UVA credentialing and privileging committee and UVA's teleradiology program.

At this meeting, telemedicine leaders made clear to CMS officials that there were two serious problems with the CMS policy for the telemedicine community:

- 1. The looming July 15, 2010 deadline when TJC telemedicine guidelines were no longer permitted.
- 2. The long term issue of how to credential and privilege telehealth practitioners at the originating site, given the complexities of the process and the facilities involved.

The CMS Proposed Rule for Credentialing and Privileging Telehealth Practitioners

CMS responded to the information they received from the telemedicine community by taking two actions to address the problem of credentialing and privileging in telemedicine.

First, in a May 21, 2010 letter, CMS notified TJC that they were extending until no later than March 1, 2011 the required compliance with the CMS CoP that would have been required as of the July 15, 2010 deeming authority approval process. Thus, the July 15th compliance date was extended.

Second, on May 26th, CMS unveiled its proposed rule to implement changes in the Medicare CoPs to permit a streamlined process between originating and distant hospitals for the credentialing and privileging of telehealth practitioners.

Through these actions, many in the telehealth community have commended CMS for recognizing the bureaucratic and financial impact of the CoP requirements on telemedicine programs nationwide. In the published rule, CMS recognized the impact of these requirements by noting:

"Upon reflection, we came to the conclusion that our present requirement is a duplicative and burdensome process for physicians, practitioners, and the hospitals involved in this process, particularly small hospitals, which often lack adequate resources to fully carry out the traditional credentialing and privileging process for all of the physicians and practitioners that may be available to provide telemedicine services. In addition to the costs involved, small hospitals often do not have in-house medical staff with the clinical expertise to adequately evaluate and privilege the wide range of specialty physicians that larger hospitals can provide through telemedicine services.

CMS has become increasingly aware, through outreach efforts and communications with the various stakeholders in the telemedicine community...of the urgent need to revise the CoP in this area so that access to these vital services may continue in a manner that is both safe and beneficial for patients and is free of unnecessary and duplicative regulatory impediments."

Provisions of the Proposed Rule

CMS proposes provisions that would apply to all hospitals and CAHs participating in the Medicare and Medicaid programs. The CMS proposal revises credentialing and privileging requirements for both hospitals and CAHs "to eliminate these regulatory impediments and allow for the advancement of telemedicine nationwide while still protecting the health and safety of patients." The hospital provisions of the CMS proposed rule include:

- 1. Agreement between Originating and Distant Hospitals: An agreement between the originating and distant sites will stipulate that all current Governing Body CoP requirements [§§482.12 (a) (1-7)] are in compliance for physicians and practitioners. CMS estimates that 4,860 hospitals and 1,314 CAHs will need to develop this agreement. The agreement must stipulate that it is the responsibility of the distant site's governing body to ensure compliance with these requirements for telemedicine practitioners. The governing bodies of all Medicare-participating hospitals currently must ensure compliance with these requirements.
- 2. Granting of Privileges based on Distant Site Information: The governing body of the originating site hospital will be allowed to grant privileges based on the recommendations of its medical staff, which can rely on information provided by the distant-site hospital. The proposal would allow the hospital's medical staff to rely on the credentialing and privileging decisions made at the distant site rather than existing requirements that require the hospital's medical staff to conduct individual appraisals of its members and examine the credentials of each candidate in order to make privileging decisions.

In order for the hospital to choose the less burdensome privileging option, the originating hospital must ensure that:

- The distant site hospital providing the telemedicine services is a Medicare-participating hospital;
- The individual practitioner is privileged at the distant site hospital;
- The distant site hospital provides a current list of the practitioner's privileges;
- The distant site practitioner "holds a license issued or recognized by the State in which the hospital, whose patients are receiving telemedicine services, is located";
- The originating site hospital "has evidence of an internal review of the distant site practitioner's performance of these privileges" and sends the distant site hospitals this information for use in its periodic appraisal of the distant site practitioner. This information must include all adverse events that may result from telemedicine services provided to the hospital's patients by the distant site's practitioner and all complaints the hospital has received about the distant site practitioner.

3. <u>Traditional Credentialing and Privileging Permitted:</u> Originating hospitals may continue to performs its own appraisals of telemedicine practitioners and may continue to use the traditional credentialing and privileging process identified in current CMS regulations.

The CAH Conditions of Participation are also being changed through this proposal. CMS is proposing to change the credentialing and privileging requirements, modeled after the hospital requirements, "with almost no difference in the regulatory language." These proposed changes in CAH credentialing and privileging requirements can be found under **Agreements** (§485.616) and **Periodic Evaluation and Performance Review** (§485.641).

The CAH CoPs changes are similar to hospitals and designed to make the CAH credentialing and privileging requirements similar to hospital requirements regarding:

- Regarding state law and categories of practitioners that may be appointed to the medical staff;
- Appoint medical staff members based on recommendations of current members;
- Assurance of the approval of medical staff bylaws and other medical staff rules;
- Accountability of medical staff to governing body for quality of care provided to patients; and,
- Criteria for medical staff selection.

The proposed CAH requirements would:

- Ensure the existence of an agreement between the CAH and the distant hospital;
- Specify the CAH's governing body's responsibility to ensure the distant site hospital meets the requirements for its practitioners to furnish telemedicine services;
- Allow the CAH's governing body the option of relying on the credentialing and privileging decisions made by the distant site hospital's governing body;
- Amend the **Periodic Evaluation and Performance Review** (§485.641 (b) (4)) by adding language to allow a distant site hospital to evaluate the quality and appropriateness of the diagnosis and treatment furnished by the distant site telemedicine practitioners providing services under an agreement between the CAH and the distant site.

Issues to Consider

1. <u>State Licensure Requirement</u>: The rule specifically provides that the distant site telemedicine physician "holds a license issued or recognized by the State in which the hospital, whose patients are receiving telemedicine services, is located." Concern has been expressed, within the telemedicine community, that this language not be interpreted to mean that the physician must hold a license in each state where the physician is offering telemedicine services.

State licensure statutes vary regarding the requirements for physicians to be licensed in order to offer consultative services. In 44 states, the licensing statutes allow for consultative services provided the out-of-state physician is licensed in another state. In 27 states, out-of-state consultations are permitted, if the physician is licensed in another state and the consultations are infrequent. Only one state – Michigan – requires an out-of-state physician to hold a full medical license in the state where the patient is located if the physician is merely providing remote, consultative services.

Through this language, CMS may intend that the out-of-state physician be in compliance with the state's licensure statute (e.g. "... or recognized by the state.)" For example, this would mean that the physician would be in compliance in all states that recognize the physician's license from another state. If this is CMS's intention, it may be necessary to include additional language in the final rule to provide that clarification.

Currently, TJC recognizes the 2. Ambulatory Care facilities not included: credentialing and privileging process of accredited ambulatory care facilities. In contracting for services from ambulatory care facilities, JC accredited hospitals have had the option of relying on the credentialing and privileging processes of IC accredited ambulatory care facilities. Hundreds of physicians in ambulatory care facilities serve countless hospitals throughout the country. Many of these hospitals are often the same smaller, originating site facilities that the CMS rule is attempting to address in providing hospital to hospital flexibility in credentialing and privileging. Ambulatory care facilities are not included in the proposed rule. Those hospitals relying on the credentialing and privileging decisions of ambulatory care facilities will be required to conduct their own credentialing and privileging process, with the same impediments of financial and staff resources and potential lack of expertise in the specialty provided by the ambulatory care practitioner. CMS should be encourage to take the next step to outline a process whereby originating site hospitals are able to rely on the credentialing and privileging done ambulatory care facilities meeting enhanced criteria.

3. <u>Liability and exposure</u>: Specialists in the area of risk management have identified areas in the proposed rule that may impact liability and exposure. It is important to note that this rule does not create these "new" liability and exposure issues, because the credentialing and privileging by proxy process has been in place since 2004. As was the case since 2004 when TJC telemedicine standards were implemented, there are liability issues to consider for the hospitals entering into a telemedicine agreement, such as corporate liability under state statute, director and officer exposure and/or liability, the possibility of enterprise liability under state statute, and the impact of this credentialing and privileging process on liability insurance coverage for health professionals.

Conclusion:

Through the involvement and input of many in the telemedicine community and the willingness of CMS to engage in a constructive and productive dialogue to reach a compromise on the issue of credentialing and privileging telemedicine practitioners, this proposed rule is available for public comment. CMS has indicated that all comments will be reviewed and addressed in the publication of the final rule.

It is important that all telemedicine practitioners, hospitals, and programs review this rule carefully for its impact on individual telemedicine programs, as well as practitioners and offer suggestions to CMS on how this issue may best be addressed.

Ensuring patient safety, while streamlining the delivery of telemedicine services are two goals that are commonly shared. Whether this proposed CMS rule meets those objectives is the question for the telemedicine community.